

GUIDE FOR APPLICANTS FOR A RADIOACTIVE MATERIAL LICENSE

1. GENERAL

1.1 Radiation Control Law Added to Health and Safety

In 1961, the Radiation Control Law was added to the California Health and Safety Code (Sections 114960–115225). Its purpose is to provide for the regulation of sources of ionizing radiation for the protection of the health and safety of workers and public. The law provides that radioactive material may be possessed only as authorized by a license and that inspections be made of licensees to determine compliance with the laws and regulations relating to radiation safety.

1.2 Licensing Responsibility Given to State Department of Health Services

The California Department of Health Services (CDHS) is designated as the agency responsible for issuance of licenses to use or possess radioactive materials. As the result of an agreement between the State of California and the U.S. Nuclear Regulatory Commission (NRC), the CDHS, on September 1, 1962, assumed most of the radioisotope licensing responsibilities that had theretofore been within NRC jurisdiction. The Department's program also includes the licensing of certain naturally occurring radioactive materials, such as radium and accelerator-produced isotopes, neither of which had been covered by the NRC program, as well as the registration and inspection of radiation machines. The terms of the California–NRC Agreement require, as do similar agreements between the Commission and other thus termed "Agreement States", that the California program remain generally compatible with that of the Commission, although it may differ in detail. The Department of Health Services carries on the radiation control program through its Radiologic Health Branch.

The State Division of Industrial Safety and several local health departments (Los Angeles County Health Department, Alameda County Health Department, Orange County Health Department) participate with the State Department of Health Services in its evaluation of license applications and inspections of installation.

1.3 Regulatory Framework Established in the Administrative Code

In considering applications for use of radioactive material, the primary concern of the Department is health and safety. The specific criteria used are those embodied in the California Radiation Control regulations (California Administrative Code, Title 17, Sections 30100–30380). These regulations, insofar as they concern radioactive materials, are based on those of the Nuclear Regulatory Commission (Code of Federal Regulations, Title 10).

1.4 Applicants to be Familiar With Regulations

Every applicant for a radioactive material license must familiarize themselves with the California Radiation Control regulations; especially those sections relevant to their own proposed use of radioisotopes. California law requires that every radioactive material licensee have available a current copy of the regulations.

2. PRINCIPAL FEATURES OF LICENSURE

2.1 Programs, Rather Than Individuals, Are Licensed

Licenses for the use of radioactive materials are issued only when all aspects of a proposed program are complete and appear adequate to assure safe use of radioisotopes. These aspects include consideration of the training and experience of the proposed users, the kinds of uses proposed, the facilities, instrumentation, personnel monitoring, and administrative procedures. A radioactive material license cannot, therefore, be issued to an applicant merely on the basis of their personal qualifications. These and other requirements are specified in Sections 30194–5 of the regulations.

2.2 Licensure is Specific

A license authorizes use of radioactive materials in a specific way, and use of the material in a fashion not encompassed by the language of the license is not authorized. Among the elements specified in a license are the following:

- The legally responsible party (the licensee)
- The locations of use
- The duration of the license
- The nuclide and chemical or physical form
- The use to which the nuclide may be put
- The maximum quantity of the nuclide which may be possessed
- The individuals authorized to use the material
- The individuals responsible for radiation safety
- The statements of the applicants to which they are held by the license

2.3 Documentation Required

The issuance of a California radioactive material license is contingent upon a satisfactory determination with respect to three key elements. These elements are:

- The capabilities of the personnel for the work proposed;
- The adequacy of the proposed procedures for protecting health and safety; and
- The suitability of the facilities for the operations proposed.

It is essential that this information be documented to enable the Department to make and support findings.

2.4 Every Independent User to be Designated on the License

Each individual who will use radioactive material under his or her own cognizance and upon their own initiative must be specified as a proposed user in the license application. Such an individual must be sufficiently qualified to bear primary radiation safety responsibility for their own work and to assure compliance with all relevant requirements.

2.5 Licensee Distinguished From Authorized User

The name that appears in Item 1 of a license is the designated licensee and is the legally responsible party to whom and in whose name the license is issued. In general, this name will not distinguish to whom isotope authorization is granted. Authorized users are designated in a condition of the license.

2.6 License Subject to Conditions Specified Therein

Licenses are issued subject to all the requirements of the California Radiation Control regulations and to the conditions specified in the license. Licenses are also subject to any additional requirements of the Department as stated in letters issued by the Department. Where a license condition or requirement letter differs from the regulations, the condition or letter is intended to supersede the regulations insofar as that license is concerned.

Items 1 through 9 of a license set forth, generally speaking, the authorizations that are granted. Conditions numbered from 10 forward specify the circumstances under which the authorizations are valid or indicate special requirements or exceptions.

A significant condition included in any license is that one, which incorporates by reference the "statements, representations, and procedures," set forth by the applicant in their license, application, or other documents specified in the condition. Therefore, any change in an isotope program which would make untrue a statement made earlier in an application or related document requires that the licensee notify the Department and request an appropriate amendment.

2.7 Licenses Subject to Annual Fees

The basic financial support for the radioactive material licensing and inspection program is obtained from fees paid by licensees, as provided by the Radiation Control Law (Section 115065, Health and Safety

Code). The fee schedule contained in the Radiation Control regulations (Sections 30230–30232) was adopted by the State Board of Health.

In order to minimize fees, the possession limits requested in an application should not be higher than foreseeable needs require. The limits may later be increased, if required, by amendment of the license. Although licenses are issued for a period of several years, the fee is an annual one, which becomes due each year on the anniversary date of issuance of the original license. A reminder notice is sent to licensees approximately 30 days prior to the anniversary date, but responsibility for timely payment rests with the licensee.

3. LICENSE APPLICATION PROCEDURES

3.1 New Applications and Application for Renewal

An applicant applying for the first time or an applicant wishing to renew a California radioactive material license must complete the items on form RH 2050, in detail, as suggested in these instructions.

3.2 Applications to Amend

An applicant desiring to amend an existing California radioactive material license must complete Items 1, 2, 12, and all other items, which provide for information pertinent to requested amendments and any other items in which there are changes in information submitted in previous applications.

3.3 Complete Applications Required

All applications must contain sufficient information to permit an evaluation to ensure health and safety. An incomplete application necessitates needless effort on the part of both the applicant and the licensing agency. Before completing an application form, applicants are urged to familiarize themselves with these instructions and with applicable provisions of California Radiation Control regulations.

In preparing a license application form, provide full and complete information that is accurate and unambiguous. In many cases, the blank spaces provided will not be sufficient to allow inclusion of adequate information. Do not hesitate to use supplemental sheets. Support material, such as radiation safety manuals, standard operating procedures, emergency procedures, and the like, should be submitted with applications.

3.4 Two Copies of Application to be Submitted to Department

Two copies of completed applications **and all supporting and supplemental material** should be sent to: California Department of Health Services, Radiologic Health Branch, MS 7610, Licensing Section, P.O. Box 997414, Sacramento CA 95899-7414.

4. EXPLANATION OF FORM RH 2050 BY PART NUMBER

1. The applicant is the organization or person legally responsible for possession and use of radioactive material specified in the application.
2.
 - a. Self explanatory.
 - b. Indicate street addresses at which radioactive material will be used if different from that listed in 1a. A post office box number is not acceptable. If radioactive material is to be used at temporary job sites, a statement to that effect should be included.
 - c. Self explanatory.
3.
 - a. List by name each radionuclide desired, such as Carbon-14, Cobalt-60, etc.
 - b. List chemical and/or physical form for each radionuclide. See note on page 4.
 - c. Specify the maximum quantity of each radionuclide that the applicant desires to possess at any one time. Units must be specified as pounds for source material, grams for special nuclear material, milligrams for radium, and curies or millicuries for all others. See note below.

NOTE: If more than one chemical or physical form of a particular radioisotope is desired, a separate possession limit should be stated for each form. For example, an applicant desiring to use two chemical forms of Iodine-131 should specify both forms and a possession limit for each form. Example:

Nuclide	Chemical and/or Physical Form	Possession Limit
(1) Iodine-131	Sodium Iodide	10 millicuries
(2) Iodine-131	Monoiodobenzene	1 millicurie

If the radioactive material is to be obtained as a sealed source, specify the manufacturer, model number, and amount of activity in *each* sealed source or of the device employing such source. Example:

(3) Cobalt-60	Sealed Sources (Iso Corp. Model Z-54)	200 millicuries in 3 sources not to exceed 100 millicuries each
---------------	--	---

- State the use of each radioactive material and chemical form specified in Item 3. If radioactive material is in the form of a sealed source, include the make and model number, if any, of the storage container and/or device in which the source will be stored and/or used. For uses of unsealed radioactive sources, describe in detail the process or processes in which the radioactive material will be used, indicating the maximum amount of radioactive material involved in each step of the process at any one time. The amount of detail required in this item will vary with the proposed use. It is essential, however, that sufficient detail be submitted in order to evaluate the use in terms of health and safety. Each type of use should be described separately and should be keyed to items listed in 3, above.
- It is necessary that there be a radiation safety officer having sufficient training and experience to assure that the radiation safety program is adequate for the purpose or use proposed. Indicate authority and responsibility delegated to this person and their position in the organization. The individual user is the person immediately responsible for the operations described and must be appropriately experienced in use and safe handling of radionuclides.

Form RH 2050 A, Statement of Training and Experience, must be submitted for the radiation safety officer and for each person named as an individual user.

- The makes and model numbers of instruments to be used in making radiation protection measurements should be specified. Each instrument must be described, e.g., Portable G.M., end window, Iso Measure Model A; Portable Gas Proportional alpha, Iso Measure Model B; Pocket Dosimeter, 0-0.2R, Iso Measure Model C; Air Sampler, Iapet, Iso Measure Model D; Scaler Amplifier-discriminator, H.V. Power Supply, Iso Measure Model E; analyzer, 512 channel, Iso Measure Model F.

The number available must be specified for each instrument described. The purpose for which each instrument will be used must be indicated, e.g., contamination, surveys, personnel monitoring, counting of wipe samples, collection of breathing zone air samples, analyses of air samples.

- If a firm or consultant will calibrate instruments, this should be explained and the name and address specified.
- The method of processing and calibrating should be discussed or the supplier of the service should be named. Frequency of bioassay and film dosimeter change should be discussed in procedures.

If an applicant plans to engage in isotope radiography, each user must be supplied with and use a film badge dosimeter and either a pocket dosimeter or pocket chamber. Pocket dosimeters and pocket chambers used by radiographers must be capable of measuring at least 200 millirems.

Procedures must require that pocket devices be read and doses be recorded daily. Pocket dosimeters and chambers should be described as in Part 6.

9. Facilities and equipment that will be used to protect health and minimize danger to life or property must be described. These descriptions must be related to operations described in Part 4. Photographs and annotated sketches or drawings should be included.
10. The radiation safety program must be described. This description must include complete radiation safety operating and emergency procedures. If sealed sources are to be used, procedures for leak testing these sources must also be specified.
11. Describe all data, measurements, calculations, and procedures used to assess the radiologic impact of effluent releases upon the general public. For all uses of unsealed radioactive materials exceeding 10⁴ times the exempt quantities listed in California Radiation Control regulations, Section 30356, Appendix B, consider annual throughput and a design basis accident.
12. If a specifically licensed, commercial waste disposal service is employed, specify the name of the company. Otherwise, submit a detailed description of methods that will be used for disposing of radioactive waste and estimates of the type and amount of activity involved.
13. Plans for decontamination and decommissioning must be described. Identify transfer or disposal procedures taken before decommissioning and whatever facility surveys are needed to establish contamination-free environment. For significant decontamination efforts describe methods, disposal procedures, and funding plans.

5. EXPLANATION OF FORM RH 2050 A BY PART NUMBER

1. Self explanatory.
2. Describe the nature of the proposed use and relate this description to Part 4, form RH 2050.
3.
 - a. Self explanatory.
 - b. Self explanatory.
 - c. List all education specifically applicable to use of radioactive material (i.e., characteristics of ionizing radiation and its radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation). Describe each program, indicating whether on-the-job or formal; specify dates, total hours, and location.
4.
 - a. Summarize experience in use of radioactive material or other source of radiation beginning with the most recent. Specify dates, describe duties, and provide the name and location of employers.
 - b. Cite typical radioisotopes handled in appropriate column and key to Part 4.a.
 - c. Identify procedures similar to those described in Part 2 with which you have had experience. Indicate number of months or years for each similar procedure and key to Part 4.a.
 - d. Self explanatory.

For more information, go to www.dhs.ca.gov/rhb or phone (916) 327-5106